codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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TO: Codex Contact Points
Interested International Organizations

FROM: Secretary, Codex Alimentarius Commission
Joint FAO/WHO Food Standards Programme
FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy

SUBJECT: **REQUEST FOR COMMENTS ON THE DRAFT REVISED STANDARD FOR GLUTEN-FREE FOODS AT STEP 6**

DEADLINE: **1 June 2006**

COMMENTS:

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BACKGROUND

The Draft Revised Standard for Gluten-Free Foods had been considered during several sessions of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) without much progress during last sessions as there was no consensus on the gluten-free levels and the method of determination.

The 49th Session of the Executive Committee decided that the draft revised Standard for Gluten–Free Foods be held until such time as the scientific basis for the establishment of gluten levels and the method of determination were clarified.

The last 27th Session of the Committee noted that the Codex Committee on Methods of Analysis and Sampling (CCMAS)[1] had endorsed temporarily the R5 ELISA method for the determination of gluten as a

[1] ALINORM 05/28/23, paras 66-72.

Type I method. The Committee was unable to discuss the Draft Revised Standard for Gluten-Free Foods due to time constraints, therefore the Committee agreed to return the latest version of this Standard to Step 6 for comments and consideration at the next session of the Committee to be held in Chiang Mai, Thailand, 30 October – 3 November 2006.

Governments and international organizations are invited to submit their comments on the Draft Revised Standard for Gluten-Free Foods and should do so in writing preferably by email to the above addresses **before 1 June 2006** (see Annex).

ANNEX

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DRAFT REVISED STANDARD FOR GLUTEN-FREE FOODS (CODEX STAN 118-1981, AMENDED 1983) AT STEP 6 OF THE PROCEDURE[2]

1. SCOPE

1.1 This standard applies to those foodstuffs and ingredients which have been especially processed or prepared to meet the dietary needs of persons intolerant to gluten.

1.2 The standard refers only to the special dietary purpose for which these foodstuffs and ingredients are intended.

2. DESCRIPTION

2.1 Definition

"Gluten-free" foods are foodstuffs so described:

a) consisting of or made only from ingredients which do not contain any prolamins from wheat or all *Triticum* species such as spelt (*Triticum spelta* L.), kamut (*Triticum polonicum* L.) or durum wheat, rye, barley, [oats] or their crossbred varieties with a gluten level not exceeding [20 ppm]; or

b) consisting of ingredients from wheat, rye, barley, oats, spelt or their crossbred varieties, which have been rendered "gluten-free"; with a gluten level not exceeding [200 ppm]; or

c) any mixture of the two ingredients as in a) and b) with a gluten level not exceeding [200 ppm]

2.2 Subsidiary Definitions

2.2.1 Gluten

For the purpose of this standard "gluten" is defined as a protein fraction from wheat, rye, barley, [oats] or their crossbred varieties and derivatives thereof, to which some persons are intolerant and that is insoluble in water and 0.5M NaCl.

2.2.2 Prolamins

Prolamins are defined as the fraction from gluten that can be extracted by 40 - 70% of ethanol. The prolamin from wheat is gliadin, from rye is secalin, from barley hordein and from oats avenin.

It is however an established custom to speak of glutensensitivity. The prolamin content of gluten is generally taken as 50%.

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 Gluten-free

For the purpose of this standard "gluten-free" means that the total content of gluten in products defined in 2.1a) shall not exceed [20 ppm], that the total content of gluten from wheat, rye, barley, [oats] or crossbred varieties of these does not exceed [200 ppm] in these foodstuffs or ingredients defined in 2.1 b) and c) on a dry matter basis. The prolamin content of liquid food products is in the same way expressed in ppm of the original product.

3.2 "Gluten-free" foodstuffs, substituting important basic foodstuffs should supply approximately the same amount of vitamins and minerals as the original foodstuffs they replace.

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[2] **ALINORM 04/26, Appendix III.**

3.3 The product shall be prepared with special care under Good Manufacturing Practice (GMP) to avoid contamination with prolamins.

4. LABELLING

The term "gluten-free" shall be given in the immediate proximity of the name of the product.

5. CLAIMS

5.1 A foodstuff or ingredient that meets the requirement set out in Section 3.1 may be labelled "gluten-free".

6. GENERAL OUTLINE OF THE METHOD OF ANALYSIS AND SAMPLING

6.1 Determination of gluten

Enzyme-Linked Immunoassay R5 Mendez (ELISA) Method

6.2 Determination of gluten in foodstuffs and ingredients

Methods used for determination should be traceable and calibrated against an internationally accepted standard, if available.

The detection limit has to be appropriate according to the state of the art and the technical standard.

The quantitative determination of gluten in foodstuffs and ingredients shall be based on an immunologic method.

The antibody to be used should react with the cereals that are toxic for persons sensitive to gluten and should not cross-react with the other cereals or other constituents of the foodstuffs and ingredients.

The qualitative analysis as indicating presence of protein shall be based on DNA-methods or other relevant methods.

The detection limit of the method should be at least 10 ppm in the product on a dry matter basis.